

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 22 NOV 2005

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Applicant's or agent's file reference 2244/PCT	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/GB2004/004895	International filing date (day/month/year) 19.11.2004	Priority date (day/month/year) 21.11.2003	
International Patent Classification (IPC) or national classification and IPC A61M15/00			
Applicant CLINICAL DESIGNS LIMITED			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <ul style="list-style-type: none"> a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of sheets, as follows: <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand 22.06.2005	Date of completion of this report 09.11.2005
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Zeinstra, H Telephone No. +31 70 340-2824



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Box No. I Basis of the report

- With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
 - With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-5 as originally filed
6 received on 20.12.2004 with letter of 16.12.2004

Claims, Numbers

1-16 as originally filed

Drawings, Sheets

1/2-2/2 received on 06.01.2005 with letter of 06.01.2005

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
 - 3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
 - 4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-16
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-16
Industrial applicability (IA)	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Re Item V.

- 1 The following documents are referred to in this communication:
- D1 : US 5 878 917 A (REINHARD ET AL) 9 March 1999 (1999-03-09)
D2 : US 4 620 670 A (HUGHES ET AL) 4 November 1986 (1986-11-04)
D3 : US 2002/043262 A1 (LANGFORD ALAN ET AL) 18 April 2002 (2002-04-18)

2 INDEPENDENT CLAIM 1

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 (see the relevant passages indicated in the search report) discloses (the references in parentheses applying to this document):
A reservoir (1) for a source of a gaseous, gas borne or droplet substance to be used in a dispenser, the reservoir (1) having:
a major portion having a comparatively large cross-section of its substance space and
a minor portion having a comparatively small cross-section of its substance space, the reservoir (1) being translucent, and preferably transparent, at the minor portion at least, whereby a user can note a comparatively rapid depletion with use of the quantity of substance remaining when the source approaches exhaustion of the substance.
- 2.2 Also document D2 (see the relevant passages indicated in the search report) discloses all the features of claim 1.
- 2.3 Also document D3 (see the relevant passages indicated in the search report) discloses all the features of claim 1.
- 2.4 Also any "bottle" would disclose all the features of claim 1 (see also Item VIII).

3 INDEPENDENT CLAIM 15

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 15 is not new in the sense of Article 33(2) PCT.

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Document D1 (see the relevant passages indicated in the search report) discloses (the references in parentheses applying to this document):
A source (5) for a dispenser (11) of a gaseous, gas borne or droplet substance from the source (5), the source (5) having a reservoir (1) as claimed in any preceding claim.

- 3.2 Also document D2 (see the relevant passages indicated in the search report) discloses all the features of claim 15.
- 3.3 Also document D3 (see the relevant passages indicated in the search report) discloses all the features of claim 15.

4 INDEPENDENT CLAIM 16

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 16 is not new in the sense of Article 33(2) PCT.
Document D1 (see the relevant passages indicated in the search report) discloses (the references in parentheses applying to this document):
A dispenser (11) for a gaseous, gas borne or droplet substance having a source (5) of the substance as claimed in any preceding claim
- 4.2 Also document D2 (see the relevant passages indicated in the search report) discloses all the features of claim 16.
- 4.3 Also document D3 (see the relevant passages indicated in the search report) discloses all the features of claim 16.

5 DEPENDENT CLAIMS 2-14

Dependent claims 2-14 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

- 5.1 In particular:
 - the features of claims 2-10 are disclosed in combination with the features of claim 1 in document D1 (see the relevant passages indicated in the search

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report). Therefore the subject matter of claims 2-10 is not new.

- the features of claims 11-14 are disclosed in combination with the features of claim 1 in document D2 (see the relevant passages indicated in the search report). Therefore the subject matter of claims 11-14 is not new.

- 6 The reservoir described in claim 1, the source described in claim 15 and the dispenser described in claim 18 are industrially applicable, and therefore the requirements of Article 33(4) PCT are met.
- 6.1 Dependent claims 2 to 14 are preferred embodiments of claim 1. In view of that, claims 2 to 14 meet the requirements of Article 33(4) PCT as well.

Re Item VII.

- 7 Independent claims 1, 15 and 16 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
- 8 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
- 9 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Re Item VIII.

- 10 The terms "large" and "small" used in claim 1 are vague and unclear and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claim unclear, Article

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6 PCT.

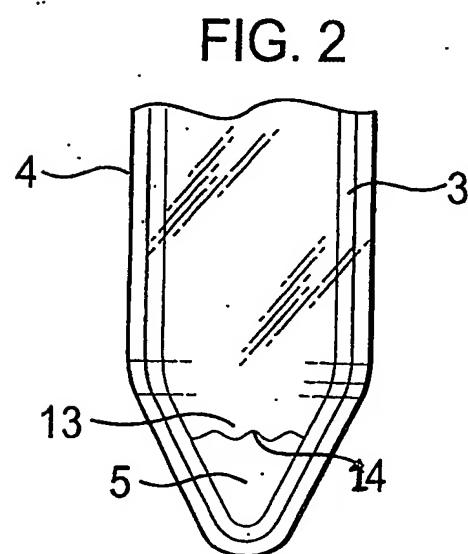
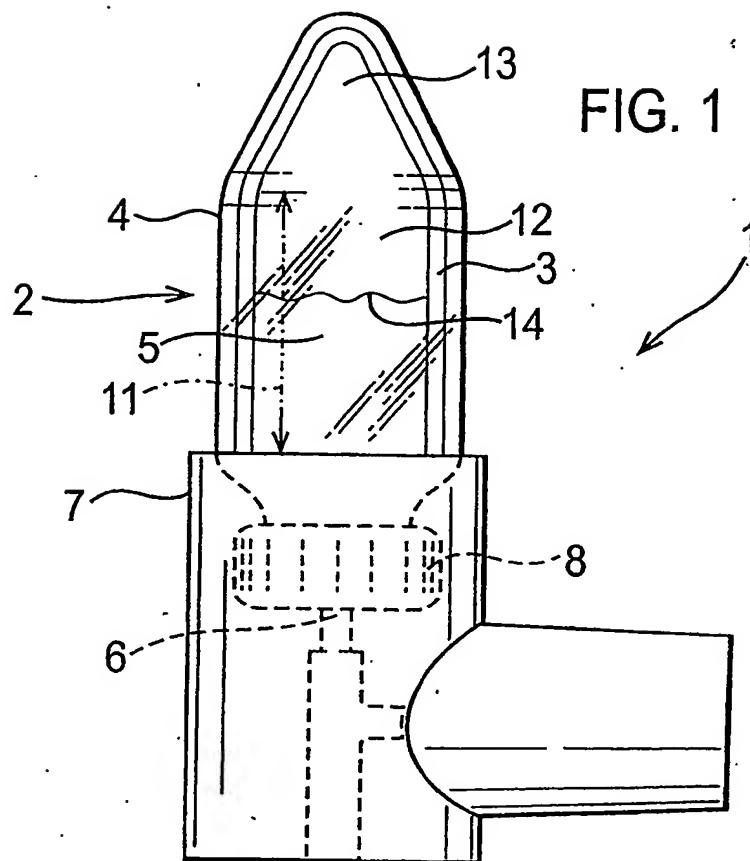
- 11 According to the requirements of Rule 10.2 PCT, the terminology and the signs shall be consistent throughout the application. This requirement is not met in view of the use of the expressions "cover" in the description and "enclosure" in claim 10 for the same feature.
- 12 The subject matter of dependent claims 4, 5, 12 is not clear (Article 6 PCT) since it is defined in relation to features (see "source", "valve" and "dispenser") not forming part of the claim. They are only "suitable for".
 - 12.1 In particular,
 - the feature of claim 4 "the source from its release valve, ...the dispenser valve up" is not defined,
 - the feature of claim 5 "the valve end" is not defined,
 - the feature of claim 12 "the valve in the source" is not defined.
- 13 Independent claim 16 defines "a source as claimed in any of the preceding claims". Since "a source" is only defined in claim 15, the definition of claim 16 is not clear, Article 6 PCT.

2.0 DECEMBER 2004

Turning now to Figure 4, the dispenser 201 thereshown again has a parallel glass reservoir 203. Within it is a translucent plastics material lining 224 of a shape essentially similar to that of the reservoir 3, i.e. with a tip 213 of lesser cross-section. The exhaustion level can be observed in this also.

06 JANUARY 2005

1/2



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